

## CLAIMS

1-32. (Canceled)

33. (Currently Amended) A method of monitoring subject compliance in a clinical trial, comprising:

detecting an event related to data entry in a paper diary for recording data using electronic instrumentation incorporated into the paper diary; and

capturing and storing a characteristic of the event to generate an electronic record of said data entry using the electronic instrumentation incorporated into the paper diary[.];

wherein said paper diary is a binder;

wherein said electronic instrumentation is incorporated into an outer casing of the paper diary and is hidden from a subject's view[.];

wherein the electronic instrumentation includes a sensor for detecting when a subject uses the paper diary.

34. (Original) The method of claim 33, wherein said step of detecting an event comprises detecting when the paper diary is opened.

35. (Original) The method of claim 33, wherein said step of detecting an event comprises detecting when the paper diary is closed.

36. (Original) The method of claim 33, wherein said step of detecting an event comprises detecting when a subject opens the paper diary.

37. (Original) The method of claim 33, wherein the step of detecting an event comprises detecting when a subject closes the paper diary.

38. (Original) The method of claim 33, wherein said characteristic comprises a time of the event.

39. (Original) The method of claim 33, wherein said characteristic comprises a date of the event.

40. (Original) The method of claim 33, wherein said event comprises use of the paper diary to record data.

41. (Original) The method of claim 40, wherein said electronic record stores the time and date of the use of the diary.

42. (Currently Amended) A method of confirming data obtained in a clinical trial, comprising: generating an electronic record containing information regarding use of a paper diary for recording clinical trial data using electronic instrumentation incorporated into the paper diary; and comparing said electronic record with written clinical trial data in the paper diary[,] ;

wherein said paper diary is a binder;

wherein said electronic instrumentation is incorporated into an outer casing of the paper diary and is hidden from a subject's view[.];

wherein the electronic instrumentation includes a sensor for detecting when a subject uses the paper diary.

43. (Currently Amended) The method of claim 42, wherein the electronic instrumentation generates an electronic record ~~records a~~ at time when a subject uses the diary.

44. (Original) The method of claim 43, wherein the subject writes a time corresponding to diary use in the diary.

45. (Original) The method of claim 44, wherein said written clinical trial data is considered valid if the time written by the subject corresponds to the time in the electronic record when the subject uses the diary.

46. (Original) The method of claim 44, wherein said written clinical trial data is considered falsified if the time written by the subject does not correspond to the time in the electronic record when the subject uses the diary.

47. (Currently Amended) A method of monitoring subject compliance in a clinical trial, comprising;

providing a subject with an instrumented paper diary for recording clinical trial data; and tracking the subject's use of the instrumented paper diary using electronic instrumentation incorporated into the instrumented paper diary[,] ;

wherein said paper diary is a binder;

wherein said electronic instrumentation is incorporated into an outer casing of the paper diary and is hidden from a subject's view[.];

wherein the electronic instrumentation includes a sensor for detecting when a subject uses the paper diary.

48. (Original) The method of claim 47, wherein the step of tracking the subject's use comprises generating an electronic record of when the subject uses the instrumented paper diary.

49. (Original) The method of claim 48, wherein the subject writes the clinical trial data and a time corresponding to the clinical trial data in the instrumented paper diary.

50. (Original) The method of claim 49, further comprising the step of comparing the time corresponding to the clinical trial data written by the user with information in said electronic record to confirm whether a time written in the diary corresponds to use of the diary.

51. (Currently Amended) A method of making an instrumented paper diary for use in a clinical trial, comprising:

providing a paper diary including paper forms for a user to record data; providing electronic instrumentation for tracking use of the diary; and incorporating said electronic instrumentation into the paper diary to record when the diary is in use[.] ;

wherein said paper diary is a binder;

wherein said electronic instrumentation is incorporated into an outer casing of the paper diary and is hidden from a subject's view[.] ;

wherein the electronic instrumentation includes a sensor for detecting when a subject uses the paper diary.

52. (Canceled)

53. (Canceled)

54. (Previously Presented) The method of claim 33 or 42, wherein said electronic record comprises at least a time corresponding to when a sensor detects that a subject uses the paper diary.